Remarks

Introduction

Claims 1-9, 17-26, and 28-29 were pending. By way of this response, claims 1 and 17 have been amended, claim 26 has been cancelled without prejudice, and claims 30-33 have been added. Support for the amendments to the claims and the new claims can be found in the specification as originally filed (e.g., examples 1-6(e)). Care has been taken to avoid adding new matter. Accordingly, claims 1-9, 17-25, and 28-33 are currently pending.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-9 and 17-26 have been rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to be described in the specification. The Office Action indicates that this is a new matter rejection.

Applicant does not agree that the subject matter of the claims was not described in the specification. However, claims 1 and 17 have been amended as set forth above to more clearly comport with the language of Example 1, and claim 26 has been cancelled. Applicant traverses the rejection as it relates to the present claims.

The claims have been amended by deleting the term "reference composition" in claims 1 and 17, which was objected to by the Examiner. Applicant submits that the subject matters of claims 1 and 17 are properly described in the specification,

including Example 1 (page 11, lines 27-32). Applicant submits that claim 30, and the claims dependent therefrom, do not include the language objected to by the Examiner, and therefore, applicant submits the rejection does not apply to claim 30, or the claims dependent therefrom.

In view of the above, applicant submits that the present claims, and claims 1-9 and 17-25 in particular, satisfy the requirements of 35 U.S.C. § 112, first paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1-9 and 17-26 have been rejected under 35 U.S.C. § 112, second paragraph regarding the use of the phrase "reference composition".

Applicant disagrees that "reference composition" renders the claims indefinite. However, the phrase "reference composition" has been deleted from the present claims, and claim 26 has been cancelled.

In view of the above, applicant submits the rejection is moot in view of the amendments to the claims.

Rejections Under 35 U.S.C. § 103

Claims 28-29 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ludlow et al. and Schantz et al. in view of Sugiyama.

Applicant traverses the rejections.

Ludlow et al. discloses treatment of torticollis by administering botulinum toxin type F to patients who have antibodies to botulinum toxin type A. Ludlow discloses a composition which comprises only one type of botulinum toxin, i.e., botulinum toxin type F. Ludlow discloses a method of treating a patient by administering botulinum toxin type F to a patient at a different time (i.e., not simultaneously) than botulinum toxin type A, for example, botulinum toxin type F is administered to the patients after the patients received botulinum toxin type A therapy.

Schantz et al. is a review article discussing the therapeutic effectiveness of botulinum toxin type A.

Sugiyama discloses forms of botulism and some structural and biological properties of botulinum toxins and tetanus toxin. Sugiyama generally discloses that there are seven known serotypes of botulinum toxin (i.e., toxin types A-G), and discusses structural and biological properties of botulinum toxins. Importantly, Sugiyama does not disclose, teach, or even suggest any therapeutic effects provided by botulinum toxin or how such toxins can be clinically used, let alone therapeutic compositions comprising one or more botulinum toxins, or even therapeutic compositions comprising two or more botulinum toxins.

The Office Action acknowledges that the combination of Ludlow et al. and Schantz et al. does not disclose a composition comprising a combination of botulinum toxin types A and B, or a

combination of botulinum toxin types A and E. The Office Action indicates that it would be obvious to a person of ordinary skill in the art to combine botulinum toxin types A and B or botulinum toxin types A and E since Sugiyama discloses that there are seven known serotypes of botulinum toxin.

Applicant vigorously disagrees, and submits that the prior art, including the combination of Ludlow et al., and Schantz et al. in view of Sugiyama provides no motivation or incentive whatsoever for a person of ordinary skill in the art to combine botulinum toxin types A and B or botulinum toxin types A and E in a single therapeutic composition.

As discussed above, Sugiyama only includes a general disclosure of botulinum toxin types A through G. Sugiyama does not disclose or even remotely suggest any clinical effects or therapeutic use of botulinum toxins. Sugiyama does not disclose, teach, or even suggest any therapeutic composition comprising a botulinum toxin, let alone, any composition that specifically comprises a botulinum toxin type A and botulinum toxin type B, or a botulinum toxin type A and a botulinum toxin type E, as recited in claims 28-29.

The motivation or suggestion to properly support a rejection under 35 U.S.C. § 103 must be clear and particular (*In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999); emphasis added), and "particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed" (*In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000)). Applicant

respectfully submits that the prior art fails to provide a clear and particular showing that one of ordinary skill in the art would have been motivated to combine the deficient teachings of Ludlow et al., Schantz et al., and Sugiyama for any purpose, let alone to combine them and obtain the claimed compositions.

Applicant submits that the listing of several different neurotoxins, including botulinum toxin types A through G and tetanus toxin, by Sugiyama provides no more than speculation of potential types of neurotoxins which are associated with poisoning, such as botulism. The general disclosure by Sugiyama of the different serotypes of botulinum toxin does not provide any motivation or incentive to a person of ordinary skill in the art to combine Ludlow et al., Schantz et al., and Sugiyama for any purpose, let alone to combine Ludlow et al., Schantz et al., and Sugiyama and specifically provide botulinum toxin types A and B, or A and E, in a single therapeutic composition, as recited in claims 28-29.

Applicant submits that, based on the teachings of Ludlow et al., Schantz et al., and Sugiyama, alone or in any combination, a person of ordinary skill in the art would still be required to guess, test, speculate, and/or arbitrarily "pick and choose" two specific neurotoxins (e.g., botulinum toxin types A and B or A and E) from among the list of seven different botulinum toxins identified by Sugiyama, as recited in claims 28-29. Sugiyama does not place any significance whatsoever in the types of botulinum toxin, let alone in a combination of botulinum toxin types A and B, or A and E, relative to the other botulinum toxins disclosed.

Simply put, the general disclosure in Sugiyama of botulinum toxin A through G is insufficient for Sugiyama, alone or in any combination with Ludlow et al. and Schantz et al., to teach or suggest the compositions recited in claims 28-29. For example, the general disclosure of botulinum toxin types A through G is insufficient for Sugiyama, alone, or in combination with Ludlow et al. and Schantz et al., to teach or suggest a therapeutic composition comprising botulinum toxin types A and B or botulinum toxin types A and E, as recited in claims 28 and 29, respectively.

Only after knowing of applicant's invention and disclosure would one of ordinary skill in the art select and combine botulinum toxin types A and B, or A and E, in a single composition from among the seven different botulinum toxins disclosed by Sugiyama, as recited in claims 28-29. Applicant submits that such hindsight is an improper basis for rejecting patent claims.

Regarding claims 30-33, applicant submits that the prior art, including the combination of Ludlow et al., Schantz et al., and Sugiyama does not disclose, teach, or suggest the claimed compositions of claims 30-33. For example, applicant submits that the prior art does not disclose, teach, or even suggest a composition comprising a first neurotoxin and a second neurotoxin (such as two or more neurotoxins), wherein the first neurotoxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F, and G, and the second neurotoxin is a different botulinum toxin than the first neurotoxin, and wherein the first and second neurotoxins are provided in different amounts in the composition, as recited in claim 30.

In addition, applicant submits that the prior art does not disclose, teach, or even suggest the composition of claim 30, wherein the amount of the first neurotoxin is greater than the amount of the second neurotoxin, as recited in claim 31. As discussed above, applicant submits that the prior art does not disclose, teach, or even suggest a single composition comprising two or more different botulinum neurotoxins, let alone, disclose, teach, or suggest the specific amounts of the botulinum neurotoxins, as recited in claims 30 and 31.

Furthermore, as discussed above, applicant submits that the prior art does not disclose, teach, or even suggest a single composition comprising the specific combination of botulinum toxin types A and B, or botulinum toxin types A and E, as recited in claims 32 and 33.

In view of the above, applicant submits that the present claims, and claims 1-9, 17-25 and 28-33 are unobvious from and patentable over Ludlow et al., Shantz et al., and Sugiyama, alone or in any combination, under 35 U.S.C. § 103.

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods and compositions including the additional feature or features recited in any of the present dependent claims, such as the specific combinations of neurotoxins. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

Conclusion

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. § 112, and are unobvious from and patentable over the prior art under 35 U.S.C. § 103. Therefore, applicant submits that the present claims, that is claims 1-9, 17-25, and 28-33 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,

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